S P E C I F I C A T I O N

TITLE

"CLOSED-END INFUSION CATHETER WITH AN INTRODUCER AND A METHOD FOR USING THE SAME"

BACKGROUND OF THE INVENTION

The present invention generally relates to a closed-end infusion catheter. The closed-end infusion catheter (hereinafter "catheter") may be porous having holes in which to infuse a body area of the patient with an anesthetic. An introducer allows for introducing the closed-end infusion catheter into the body and proper placement of the catheter. In addition, the present invention provides a method for placing a catheter in a body of a patient.

It is, of course, generally known to use a catheter to apply anesthetic locally to different areas of the body. Various types of catheters as well as methods for inserting and securing catheters are also known. For example, in U.S. Patent No. 5,735,829 to *Cherian*, a catheter is inserted during thoracic surgery by a surgeon. The catheter disclosed by *Cherian* has a plurality of spaced ports such that anesthetic is delivered directly to the intercostal nerves. In U.S. Patent No. 5,141,499 to *Zappacosta*, a peritoneal dialysis catheter is disclosed. The peritoneal dialysis catheter disclosed in *Zappacosta* carries one to two porous cuffs to facilitate permanent securance of the catheter to the abdominal wall. The catheter has a plurality of flow ports, and its end may be open as well for additional flow communication.

However, use of such known catheters often results in a significant problem with the risk of post-operative infection and discomfort to the patient.

A need, therefore, exists for a device, an introducer and a method designed to quickly and to efficiently distribute anesthetic to a patient by use of a catheter.

SUMMARY OF THE INVENTION

The present invention provides an introducer for a catheter and a closed-end infusion catheter (hereinafter "catheter"). The catheter may be porous with a number of holes in which to infuse an anesthetic into a body area of the patient. The introducer allows for introducing and proper placement of the catheter. In addition, the present invention provides a method for using the introducer to properly place the catheter in the body of the patient.

To this end, in an embodiment of the present invention, a catheter introducing device for placing a catheter within a body has a cylindrical body defining a cross with a length defined between a pointed end and a flat end. The catheter introducing device also has a first part and a second part both having a uniform width and a length defined between the pointed end and the flat end. The first part defines a cross and the first part and the second part together define the cylindrical body.

In an embodiment, a locking mechanism is located at the flat end of the cylindrical body. The first part and the removable second part are locked together.

In an embodiment, the pointed end of the cylindrical

body gradually tapers to a cylindrical portion.

In an embodiment, the catheter introducing device has sufficient structural strength to penetrate through skin and into a subcutaneous layer of a body.

In an embodiment, a recessed portion is provided along the length of the first part and a protruding element defined in shape by a right angle is located along the recessed portion of the first part.

In an embodiment, a protrusion along the length of the removable second part of the cylindrical body is provided wherein the recessed portion along the length of the first part may readily accept the protrusion along the length of the removable second part.

In another embodiment of the present invention, the catheter introducing device for placing a catheter within a body has a cylinder having a length defined between a pointed end and a bottom end. The catheter introducing device also has a leg attached perpendicularly to the bottom end of the cylinder. The catheter introducing device further has a first hole located a distance from the pointed end of the cylinder and a second hole located on the leg of the cylinder. A thread is connected to the cylinder from the second hole to the first hole.

In an embodiment, a groove is cut into the cylinder and has a length defined between the first hole and the pointed end.

In an embodiment, a locking mechanism is located on the leg of the cylindrical body.

In an embodiment, the pointed end of the cylinder gradually tapers to a cylindrical portion.

In an embodiment, the cylinder has sufficient structural strength to penetrate through skin and into a subcutaneous layer of a body.

In another embodiment of the present invention, a catheter for infusing a local anesthetic has a flexible hollow body defining a length between a pointed end and a bottom end. The pointed end is closed and tapers to a cylindrical tube. The catheter further has a diameter defined by the cylindrical tube with a width defined by the bottom end of the flexible body. The width is greater than the diameter. The catheter also has a locking mechanism located on the bottom end of the flexible body, as well as a first and second notch located a distance from where the pointed end meets the cylindrical tube and a distance from the bottom end, respectively.

In an embodiment, the catheter is a flexible hollow body and is constructed of a porous material. The flexible hollow body may have a plurality of holes.

In another embodiment of the present invention, a method for introducing a catheter into the skin and the subcutaneous layer in a body of a patient is provided. The method comprises the steps of: providing an instrument; piercing the skin and the subcutaneous layer of the body with the instrument; pushing the instrument through the subcutaneous layer to an exit site outside of the body; attaching a catheter to the instrument; pulling the instrument and the catheter back into the subcutaneous layer and the entry site; removing the instrument from the catheter; and pulling the catheter

back into the subcutaneous layer.

In an embodiment, the catheter is prevented from slipping into the body and from slipping out of the body.

In an embodiment, the catheter is sutured to the skin of the body.

In an embodiment, the catheter is attached to the instrument by placing a catheter on the instrument.

In an embodiment, the catheter is secured to an instrument with a thread.

In an embodiment, the catheter is secured to an instrument by fitting the catheter to a notch on the instrument.

It is, therefore, an advantage of the present invention to provide a a catheter introducing device for placing a catheter within a body.

Another advantage of the present invention is to provide a catheter for infusing a local anesthetic.

And, another advantage of the present invention is to provide a catheter having a flexible hollow body constructed of a porous material or having a plurality of holes.

A further advantage of the present invention is to provide a locking mechanism located at the end of the catheter.

A still further advantage of the present invention is to provide a catheter introducing device that has sufficient structural strength to penetrate through skin and into a subcutaneous layer of a body.

Another advantage of the present invention is to provide a catheter introducing device with a groove cut

into the introducing device to accommodate a catheter.

A further advantage of the present invention is to secure the catheter to an instrument with a thread.

A still further advantage of the present invention is to secure the catheter to an instrument by fitting the catheter to a notch on the instrument.

Moreover, an advantage of the present invention is to provide a method for introducing a catheter into the skin and the subcutaneous layer in a body of a patient.

And, another advantage of the present invention is to prevent a catheter from slipping and to suture the catheter to the skin of the body.

Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of an embodiment of a catheter of the present invention.

Figure 2 is a plan view illustration of an embodiment of an introducer of the present invention.

Figure 3 is a cross-sectional view of an embodiment of a catheter taken along lines III-III of Figure 2 of the present invention.

Figure 4 is a cross-sectional view of an embodiment of a catheter taken along lines IV-IV of Figure 2 of the present invention.

Figure 5 is a plan view of an embodiment of an introducer of the present invention.

Figure 6 is a cross-sectional view of an embodiment

of a catheter taken along lines VI-VI of Figure 5 of the present invention.

Figure 7 is a cross-sectional view of an embodiment of a catheter taken along lines VII-VII of Figure 5 of the present invention.

Figure 8 is a cross-sectional view of an embodiment of a catheter taken along lines VIII-VIII of Figure 5 of the present invention.

Figure 9 is a cross-sectional view of an embodiment of a catheter taken along lines IX-IX of Figure 5 of the present invention.

Figure 10 is a cross-sectional view of skin and subcutaneous tissue.

Figure 11 is a cross-sectional view of an embodiment of a method of insertion of an introducer into the body of a patient.

Figure 12 is a cross-sectional view of an embodiment of a method of the introducer in the body of a patient and at the exit site of the body of the patient.

sub a1 > Figure 13 is a cross-sectional view of an embodiment of a method releasing the locking mechanism of one type of introducer.

Figure 14 is a cross-sectional view of an embodiment of a method of one type of introducer accepting a catheter.

Figure 15 is a cross-sectional view of an embodiment of a method of the removal of the introducer from the body of the patient.

Figure 16 is cross-sectional view of an embodiment of the catheter properly placed in the body of the

patient.

Figure 17 is a cross-sectional view of an embodiment of a method of attaching a catheter to an introducer.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention generally relates to an introducer for a a closed-end infusion catheter. The closed-end infusion catheter (hereinafter "catheter") preferably is porous with a number of holes in which to infuse anesthetics into a body area of a patient. The introducer allows for introducing and proper placement of the catheter. In addition, the present invention provides a system and a method for using the introducer to properly place the catheter in a body of a patient.

Referring now to the drawings wherein like numerals refer to like parts, in Figure 1, a closed-end infusion catheter 10 is generally illustrated. The catheter 10 is preferably constructed of a flexible material, such as for example, a flexible plastic. The catheter 10 preferably has a pointed end 100 and a bottom end 104. The pointed end 100 may taper to a cylindrical tube 102. The bottom end 104 of the cylindrical tube 102 preferably has a width greater than the diameter of the cylindrical tube 102. The catheter 10 preferably has a locking mechanism 114 located near the bottom end 104 of the cylindrical tube 102. A notch 106 may be located near the pointed end 100, and a second notch 108 may be located near the bottom end 104. The cylindrical tube 102 may be constructed of a porous material 110, or alternatively, with a plurality of holes 112 throughout

not shown in figure.

its length. In an embodiment, the catheter 10 may be used, for example, during cardiac surgery to deliver a local anesthetic directly to nerves of a sternum of a patient. Or, for example, the catheter 10 may be used by a paramedic to deliver local anesthetic to the knee of an injured person prior to transporting the person to a hospital.

Referring now to Figure 2, an introducer 20 is illustrated. The introducer 20 may have a cylindrical rod 202 defined by a base 204 and a pointed tip 200. The base 204 is preferably wider than the diameter of the cylindrical rod 202. The pointed tip 200 tapers to the cylindrical rod 202. The introducer 20 is preferably constructed of a material of sufficient structural strength to pierce skin, such as, for example, steel or plastic. The introducer 20 may have a first hole 208 placed in a groove 212 in the cylindrical rod 202 at a distance from the pointed tip 200 of the introducer 20. The introducer 20 has a second hole 206 at the base 204. A loop 210 may extend through the first hole 208 and the second hole 206 at either end of the introducer 20. Preferably, the loop 210 is a monofilament nylon thread. The loop 210 may enter one side of the introducer 10 and may exit in the groove 212 placed into the side of the pointed tip 200 of the introducer 20.

Figure 3 illustrates a cross-sectional view of the catheter 10 placed on the introducer 20 at the groove 212 in the cylindrical rod 202. Figure 4 illustrates a cross-sectional view of the introducer 20 at the first hole 208 in the groove 212 in the cylindrical rod 202.

In a preferred embodiment, the groove 212 accepts the catheter 10 during insertion as shown in Figure 17.

Alternatively, an introducer 50 may be designed as generally illustrated in Figure 5. The introducer 50 may be constructed of two elements that form a cylindrical cross. The introducer 50 may have a pointed end 38 and a blunt end 40. The first element 32 of the introducer is preferably a cross-shaped cylindrical rod 31 with a circular cut 34 from the blunt end 40 to a right angle notch 42. The second element 36 may fit into the circular cut 34 of the first element 32 of the introducer 50. The blunt end 40 may have grooves 44 on both the first element 32 and the second element 36. As a result, the first element 32 and the second element 36 together form a locking mechanism. Cross-sections taken along lines VI-VI, VII-VII, VIII-VIII and IX-IX are shown in Figures 6-9, respectively. Figure 6 generally illustrates a cross-section of the introducer 50 taken along its length. Figures 7-9 generally illustrate the right angle notch 42 located within the circular cut 34 of the first element 32 and the corresponding cross-section on the second element 36.

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In an embodiment of the present invention, the introducer 50 may be used to introduce the catheter 10 into a body. For example, Figure 10 illustrates skin 60 and the subcutaneous tissue 62 located under the skin 60 of a human being or patient. As shown in Figure 11, the introducer 50 may be pushed into the skin 60 at an entry site 54 and to the subcutaneous tissue 62. Figure 12 generally illustrates the introducer 50 in the

subcutaneous tissue 62 and proceeding to an exit site 56. After the introducer 50 protrudes outside the exit site 56, the catheter 10 may be attached as shown in Figure 13. A locking mechanism is formed by the grooves 44 and a cap 46. The cap 46 is removed from the blunt end 40 of the introducer 50, thereby releasing the lock between the first element 32 from the second element 36. The second element 36 of the introducer 50 may be removed.

As shown in Figure 14, the pointed end 100 of the catheter 10 may be placed in the circular cut 34 of the first element 32 of the introducer 50. The catheter 10 may be secured by placing the notch 106 of the catheter 10 at the right angle notch 42 of the first element 32. As a result, the catheter 10 and the first element 32 fit together, and the catheter 10 may be kept from slipping away from the introducer 50 while located in the subcutaneous tissue 62 of the body.

Alternatively, as shown in Figure 17, when using the introducer 20, the catheter 10 may be attached by placing the pointed end 100 of the catheter 10 on the groove 212 of the introducer 20. The notch 106 in the catheter may be aligned with the first hole 208 in the introducer 20. The loop 210 may then be secured around the catheter 10 at the notch 106 of the catheter 10.

As shown in Figure 15, after the catheter 10 is attached to the introducer 20 or 50, the introducer 20 or 50 may be pulled back into the subcutaneous tissue 62 and back through the entry site 54. The introducer 20 or 50 may then be removed, and the catheter 10 may be pulled back into the subcutaneous tissue 62 to its

desired location. The catheter 10 may then be secured in place with a suture 64 as shown in Figure 16.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be covered by the appended claims.